stryker®
ENDOSCOPY

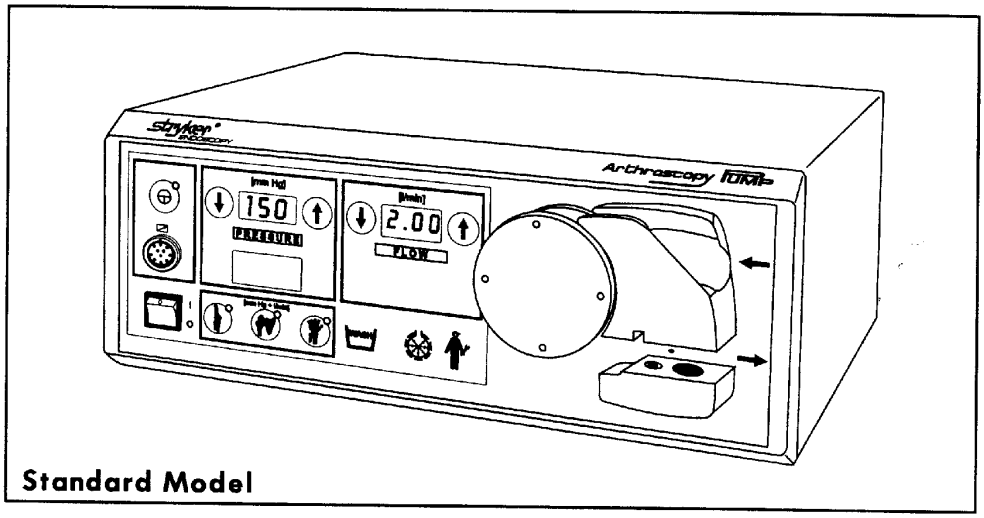
Arthroscopy PUMP

Handbuch

Manual

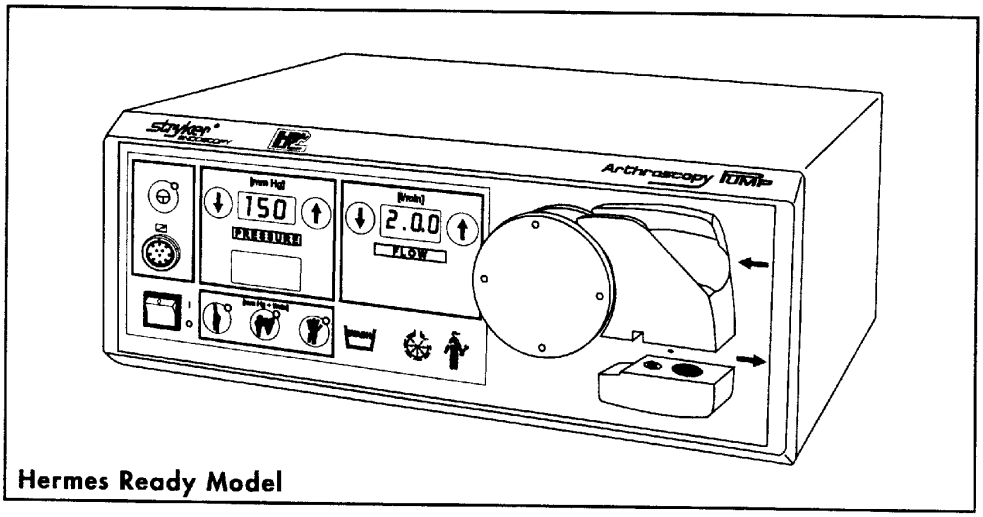
Manuel

Manual



Standard Model

Manuale



Hermes Ready Model

Spülpumpe für die Arthroskopie

Irrigation pump for arthroscopy

Pompe d'irrigation pour l'arthroscopie

Bomba de enjuague para la artroscopia

Pompa di lavaggio per l'artroscopia

GENERAL INFORMATION

E

Read this manual

Please familiarize yourself with the contents of this manual before using the device. Failure to follow these instructions may result in injuries to both the patient and the user. Medical accessories and devices may be used only by physicians or medical assistants under the direction of a physician with the appropriate technical qualification.

Please read this manual completely and follow its instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and they should be read attentively.

WARNING !
The personal safety of the patient may be involved. Disregarding this information could result in injury to the patient.

CAUTION !
These instructions point out special service procedures or precautions that must be followed to avoid damaging the device.

NOTE !
This provides special information that facilitates maintenance or clarifies important instructions.

Please pay particular attention to the chapters Safety Instructions and Purpose of the Device.

Who should use the manual ?

The manual is addressed to physicians or medical assistants with an appropriate qualification. These persons are authorized to operate this device.

The structure of the manual

The large titles in the header will help you locate the chapters quickly.

There is a list of error messages and warning indications at the end of the manual that assist in troubleshooting problems.

Refer to the illustrations on the rear cover of the manual.

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1 SAFETY INSTRUCTIONS

Please familiarize yourself with the safety instructions before using the device!

Federal law (only U.S.A.)
Federal Law (U.S.A.) restricts this device to use by or on the order of a physician.

Warranty
The manufacturer warrants that the device and the accessories will be free from manufacturing and material defects for one year from date of purchase. This warranty is limited to the terms and conditions described herein, and there are no other warranties, expressed or implied.

No liability
The manufacturer is not liable for direct or resulting damage, and the warranty becomes void if:

- the device or the accessories are improperly used;
- the instructions and rules in the manual are not adhered to;
- the device or the accessories are improperly prepared or maintenanced;
- non-authorized persons perform repairs, adjustments or alterations on the device or accessories;
- the prescribed inspection and maintenance schedule is not adhered to.

Receipt of technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments or alterations on the device or accessories.

Authorized service technician
Only an authorized service technician may perform repairs, adjustments or alterations on the device or accessories. The manufacturer has the exclusive right to train and certify authorized service technicians.

Care and maintenance
To guarantee safe operation, it is absolutely necessary to carry out proper care and maintenance of the device and accessories. For the protection of the patient and the operating team, check that the device is complete and functional before each use.

Brand-new products, as well as repaired products, must be prepared and tested according to the manual instructions prior to use.

Contamination
For the protection of the service personnel, and for safety during transportation, all devices and accessory parts that are sent in to be repaired must be prepared for shipment as described in the manual. If this is not possible, the product must be clearly marked with a contamination warning and should be double-sealed in safety foil.

The manufacturer has the right to refuse to carry out repairs if the product is contaminated.

Waste Management
Follow the national waste Management rules.

Water hazard
Protect the device from being splashed by water. Keep the power switch dry. Should any liquid enter the device, discontinue use immediately.

Original accessories
For your own safety, and that of your patient, use only original accessories.

Specific technique and procedure
Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.

Available voltage
Determine if the available voltage corresponds to your device. Working with the wrong voltage will cause the device to malfunction or may permanently damage the device.

Not explosion-proof
Electrical components are not explosion-proof. Do not use in an area where flammable gases are present.

Risk of electrical shock
To reduce the risk of electrical shock, do not remove cover (or back). Refer servicing to qualified service personnel.

Replacing fuse
For continued protection against fire hazards, replace the fuse only with a fuse of the same type and ratings.

Internal standard settings
Check all settings that are standard to your work place. Such internal standard settings are not necessarily prescribed for the doctor. The doctor is responsible for all settings that pertain to his/her operation.

Cleaning the device
Do not sterilize the device.

1-1 Warnings

Reading the manual
This manual describes the operation and the intended use of the device and the accessories.

It is essential to use this manual to familiarize yourself with the functions and the operation of the device before using it in the operating room.

1 SAFETY INSTRUCTIONS

Failure to follow these manual instructions can result in serious injury to the patient or the operating team and can lead to damage or destruction of the device and accessories.

Professional qualification
This manual does not provide a detailed description of operation techniques, nor is it suitable for introducing a beginner to this operating technique. Medical accessories and devices may be used only by physicians and medical assistants under the direction of a physician with the appropriate technical qualification.

Sterile substances and accessories
Always work exclusively with sterile substances sterile fluids and sterile accessories.

Replacement device and accessories
In case the pump fails during an operation, a replacement device and replacement accessories should be kept within reach so that the operation may be completed.

Specific device warnings
Read the warnings specific to this device under chapter: Purpose of the Device.

Function test
You must perform the function test (see Function Test chapter) before you begin each operation.

Device deficiency
If you suspect or have confirmed that the device is defective, stop using the device until it has been checked by authorized service personnel.

Endoscope
The device may only be connected to endoscopes which, in their intended use and technical specifications, are appropriate for use with the device for the intended medical procedure. The endoscopes must comply with the most recent version of DIN EN 60601-2-18 and ISO 8600.

2 PURPOSE OF THE DEVICE

Intended Use
This device provides fluid distention of articular cavities for diagnostic and /or operative arthroscopic procedures.

Such procedures may include:
- Ligament injuries
- Meniscus injuries
- Cartilage injuries
- Operation planning and re-examination

Refer to your arthroscope's operator's manual for specific indications for use.

The intraarticular pressure and flow can be preselected. Once the preselected pressure level has been reached, the device automatically interrupts the flow of fluid. If the intraarticular pressure falls below the preselected level, the fluid flow will automatically be re-initiated.

Recommended pressure
The device is indicated for use in the following joints. The listed pressure levels are generally considered appropriate, although circumstances may vary from patient to patient and procedure to procedure. These values are recommendations and are not intended to substitute or replace the expertise of the surgeon.

Knee	90 mm Hg
Shoulder	60 mm Hg
Elbow	50 mm Hg
Ankle	70 mm Hg
Wrist	60 mm Hg

Contraindications for Use
Use of this device for fluid distention is contraindicated whenever arthroscopy is contraindicated. Refer to your arthroscope's operator's manual for absolute and relative contraindications.

The device is contraindicated for:
- Ankylosis
- Inflammation or bacterial contamination of an open wound

The device is not intended for the injection of medication.

Clinical Use
When performing arthroscopic electrosurgery, the distention medium must be electrically non-conductive. Examples include glycine, sorbitol, mannitol, sorbitol plus mannitol, and dextran.

2-1 Cautions

Open the stopcocks
Failure to open the stopcocks (inflow and outflow) of the instrument completely during the recognition phase may result in inaccurate measurement of intraarticular pressure.

3 INITIAL USE OF THE DEVICE

3 INITIAL USE OF THE DEVICE

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Initial inspection

Check the device and all accessories immediately upon receipt to insure that the contents are complete and that nothing is damaged. The manufacturer will only honor claims for compensation which are forwarded immediately to the sales representative or the authorized service company.

Returning the device

If it becomes necessary to return the device, use of the original packaging is required. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging. Please enclose the following information with the device:

- owner's name
- owner's address
- device type
- serial number of the equipment (see identification plate)
- description of the damage.

Setting up the device

Place the pump on a level surface in a dry place. The ambient temperature should be between 10-40 °C (50-104 °F), and the relative air humidity should be between 30-75 %.

Power supply connection

The specifications of the mains power supply must comply with IEC, CEC, and NEC requirements.

Please refer to the back of the device (fuse holder or device label) to determine the device's operating voltage.

CAUTION !
Determine if the available voltage corresponds to your device. Working with the wrong voltage will cause the device to malfunction or may permanently damage it.

Safety plug

The power supply cable must be equipped with a safety plug. Use the enclosed power cable for the connection between the power plug and the device socket.

For the American user

Use only a listed detachable power supply cable, type SJT, minimum 18 AWG, 3 conductors, one end configured for NEMA 5-15, other end for IEC 320/CEE22.

Grounding will only be reliable if the equipment is connected to a corresponding Hospital Grade socket.

CAUTION !
The electrical components are not explosion-proof. Do not use in an area where flammable gases are present.

Potential equalization

Integrate the device into the potential equalization that corresponds to your local electrical system.

4 OPERATING THE DEVICE

4-1 Front of the Device

(1) Desired pressure display with $Pressure_{minus}$ key and $Pressure_{plus}$ key
(2) Desired flow display with $Flow_{minus}$ key and $Flow_{plus}$ key
(3) Roller wheel
(4) Pumphead with pressure sensor I
(5) Pressure sensor II
(6) Switch for pressure chamber
(7) Warning displays and display 'Wash'
(8) Actual pressure display
(9) Program keys
(10) Connection for cable remote control
(11) Power switch
(12) Start/Stop key

4-2 Rear of the Device

(1) Connection for footpedal
(2) Identification plate
(3) RS232-Serial port, connection for HERMES Ready System
(4) Connection for potential equalization
(5) Device socket
(6) Fuse box

4-3 Inserting the Tubing Set

Illustr.: 4-3/1
The sterile tubing set consists of three tubing parts ①, ②, ③, one pressure chamber ④, one tubing fixing ⑤ and one insert pin.

The parts of the tubing are specified as irrigation ①, roller ② and instrument tubings ③.

Inserting the roller tubing

Illustr.: 4-3/2
Make sure that the membranes ⑨ of the pressure chamber are not damaged when inserting the roller tubing. Ensure that there is no liquid in the tubing prior to inserting the pressure chamber.

1. Remove the safeguard for transportation from the pressure chamber.
2. Carefully slide the pressure-free pressure chamber ④ (nose ⑧ upwards) into the cutout of the pump head. The pressure chamber has to snap in audibly and shut flush with the pump head.
3. Place the roller tubing ② around the roller wheel.
4. Stretch the tubing and insert the tubing fixing into ⑤ the upper part of the pump head.

Make sure that the tubing fixing snapped in tightly.

Connecting the instrument tubing

Remove the protective cover from the instrument tubing. Connect the instrument tubing ③ to the instrument or drainage cannula.

Connecting the fluid container

The fluid container must hang 0.7-1.0 m above the device.

Close the clamp at the rinsing tubing. The irrigation tubing ① has been prepared to take in irrigation fluid from one or two irrigation container(s). Whenever a tube is connected to or disconnect from the fluid container, be sure to grasp the puncture needle at the appropriate grip. The spike, sterilized by the manufacturer, is inserted into the container in accordance with prescribed regulations for sterilization in operating rooms.

Make sure to use only fluid containers of flexible material (plastic sac).

CAUTION !
There is a danger of implosion when using glass bottles because of the vacuum which builds up in the bottle.

Provide for a sterile ventilation of inflexible containers.

WARNING !
The choice of irrigation fluid is determined by the physician based on the operation method which is to be employed.

4-4 Turning the Device on

Turn the device on using the power switch (position I=on). The actual pressure display briefly indicates '---'. The power switch, and the digital displays will light up.

The digital displays should read:

Desired pressure	0 [mm Hg]
Desired flow	0.10 [l/min]
Actual pressure	0 [mm Hg]

On delivery, the device is initially programmed with the following settings:

Desired pressure:	0 [mm Hg]
Desired flow:	0.10 [l/min]

Each time you switch the device on and off, the device saves the last entered desired pressure and flow levels and shows the values in the displays.

4-5 Start/Stop Key

Insert the tubing set (see chapter 4-3). Press the Start/Stop key. The green Start/Stop LED lights up. The roller wheel starts to turn. The actual pressure display indicates the actual value.

If the tubing set is not inserted and you press on the start/stop key, three short warning beeps will be heard and the roller wheel will not start moving.

Pressing the Start/Stop button a second time stops the roller wheel. The green Start/Stop LED goes out. The actual pressure display shows the actual value.

4 OPERATING THE DEVICE

4-6 Automatic Instrument Recognition

The device is equipped with an automatic instrument recognition feature which enables the achievement of optimal flow rates with every standard instrument on the market.

For the initialization of the automatic instrument recognition, a minimum desired pressure of 50 mm Hg and a minimum desired flow of 0.80 l/min must be preselected when starting the device. After initialization, lower pressure and flow values may be selected.

1. Connect the fluid container, tube and instrument.
2. Open the stopcocks (inflow and outflow) of the instrument completely.

WARNING !
Failure to open the stopcocks (inflow and outflow) of the instrument completely during the recognition phase may result in inaccurate measurement of intraarticular pressure.

3. Select a desired pressure of 50 mm Hg and a desired flow of 0.80 l/min. Press the Start/Stop key.
4. The device recognizes the connected instrument automatically. The roller wheel pump may briefly run at various speeds and stop for short periods.

Intraoperative instrument change

An intraoperative instrument change may only be performed after pressing the Start/Stop key. Only by pressing the Start/Stop key is the device capable of performing a new automatic instrument recognition.

1. In order to change instruments during the operation, press the Start/Stop key in order to stop the pump.
2. Connect the new instrument.
3. Open the stopcocks (inflow and outflow) of the instrument completely.
4. Press the Start/Stop key again. Instrument recognition is initiated automatically. The roller wheel pump may briefly run at various speeds and stop for short periods.

4-7 Preselecting the Desired Pressure

You can preset the desired pressure between 0-150 mm Hg. The desired pressure display shows the preselected value in mm Hg. You can control the various functions as follows:

One short press on the Pressure$_{minus}$ key:
Reduction of the desired pressure by 1 mm Hg within the whole selectable range.

One long press on the Pressure$_{minus}$ key:
Continuous reduction of the desired pressure in increments of 10 mm Hg within the whole selectable range.

One short press on the Pressure$_{plus}$ key:
Increase of the desired pressure by 1 mm Hg within the whole selectable range.

One long press on the Pressure$_{plus}$ key:
Continuous increase of the desired pressure by 10 mm Hg within the whole selectable range.

4-8 Preselecting the Desired Flow

You can preset the desired flow between 0.1-2.0 l/min. The desired flow display shows the preselected value in l/min. You can control the various functions as follows:

One short press on the Flow$_{plus}$ key:
Reduction of the desired flow by 0.05 l/min within the whole selectable range.

One long press on the Flow$_{minus}$ key:
Continuous reduction of the desired flow in increments of 0.10 l/min within the whole selectable range.

One short press on the Flow$_{plus}$ key:
Increase of the desired flow by 0.05 l/min within the whole selectable range.

One long press on the Flow$_{plus}$ key:
Continuous increase of the desired flow by 0.10 l/min within the whole selectable range.

The height of the fluid bag influences the flow rate. In order to achieve an optimal flow rate, hang the fluid bag exactly 1 meter over the device.

4-9 Program Keys

Illustr.: 4-9
With the three program keys

- Knee joint ①
- Shoulder joint ②
- Small joints ③

preselected pressure and flow values may be saved and recalled with the touch of a key. The standard on delivery values are:

- Knee joint: 70 mm Hg/1.0 l/min.
- Shoulder joint: 60 mm Hg/2.0 l/min.
- Small joints: 50 mm Hg/1.0 l/min.

You may save your own values as follows:

1. Preselect the desired pressure and flow values for the knee joint.
2. Press the 'Knee Joint' key for 5 s. The LED on the key blinks. The values are saved.
3. For the shoulder joint and small joints, proceed as described in steps 1. and 2. above.

4. Press the program key once. The saved values are displayed in the preselected flow and preselected pressure display windows.

4-10 Actual Pressure Display

The pressure is measured at the pressure chamber. The pressure display is calculated by means of the measured pressure and the following OP parameters

- hydrostatic admission pressure
- flow
- instrument resistance

and shown in the actual pressure display in millimetres mercury column [mm Hg]. Follow the instructions in Chapter 4-6, Automatic instrument detection, exactly for the best possible display accuracy of the intraarticular pressure.

4-11 Warning Displays

The warning displays 'Overpressure' and 'Service' light up only in case of a warning or malfunction of operation. Please refer to chapter Safety Function.

4-12 RS232-Serial Port (Option)

The pump is configured to be attached to the HERMES Operating Room Control Center over the RS232-serial port. As such, the pump is capable of direct surgeon control over device functions and adjustments by direct voice control or by manual use of a hand held pendant control.

It is recommended that the physician and support personnel be thoroughly familiar with the setup and operation of the HERMES Operating Room Control Center. Please refer to the HERMES Operating Room Control Center for the proper setup, use and troubleshooting of the Voice Control Interface portion of that device.

When the HERMES Operating Room Control Center is connected and active, the function parameters of the pump may simultaneously be adjusted using the keys on the front panel or remote control.

For troubleshooting or further information please refer to your HERMES Operating Room Control Center manual.

The HERMES Operating Room Control Center is manufactured by Computer Motion Inc.

The proper operation of the pump is constantly monitored electronically. Deficiencies are indicated through warning signals, warning displays, error messages and/or blocking of certain functions.

Error in the pressure measurement system
One of the two pressure sensors does not operate, or an error is detected in the pressure measurement system. The actual pressure display indicates 'E01', the warning display 'Service' lights up, a warning signal is heard, and the pump is stopped.

Turn the device off and on again after 10 s. Should the error message still occur, the device should not be used again. Refer to qualified service personnel.

The engine control mechanism is defective
If the actual pressure display indicates 'E02' and the warning display 'Service' lights up, the engine control mechanism is defective. Check if the pump is stuck.

Turn the device off and on again after 10 s. Should the error message still occur, the device should not be used again. Refer to qualified service personnel.

Incorrect location of the pressure chamber
The pressure chamber did not snap into the pump head. When pressing the Start/Stop key, three warning signals are heard and the Start/Stop LED flashes. The pump does not start.

Exceeding the desired pressure
If the actual pressure exceeds the desired pressure, the roller wheel turns back in order to reduce the pressure.

An audible warning signal is activated should the roller wheel spin backwards for an extended period of time. Fluid may be transported from the joint into the tubing set.

Exceeding the desired pressure (30 mm Hg)
If the actual pressure exceeds the desired pressure by 30 mm Hg, the actual pressure display flashes.

Exceeding the desired pressure (250 mm Hg)
If the actual pressure has reached or exceeded 250 mm Hg for more than 5 s, the actual pressure display flashes, the warning display 'overpressure' lights up, and a warning signal is heard. The roller wheel stops. The pump starts the roller wheel automatically when the pressure has fallen below 250 mm Hg.

Internal safety system
If the actual pressure display indicates error message (e.g. E02) and the warning signal 'Service' lights up, this means the pump is not functioning. The irrigation process stops or cannot be activated.

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Turn the pump off and on again after 10 s. Should the error message still occur, the device should not be used again.

The pump's internal safety system has recognized an error. Further operation is not possible.

Forbid any further use of the pump. The device must be checked by a qualified service technician.

With the user menu the parameters of the device can be changed and displayed before the operation. There are three different menu options:

P0: shows the actual software version

P1: selects the desired pressure which should automatically be activated when using the footpedal.

P2: shows the actual pressure values of the pressure sensors

How to activate the user menu

Illustr.: 6/1-6/3

1. Turn the device on using the power switch.
2. While '---' flashes in the actual pressure display ①, press on the $Pressure_{plus}$ key ②. The desired flow display will show P1. The 'P' flashes ③.
3. Press the Start/Stop key ④. 'P' stops flashing. The desired pressure display ⑤ (and possibly the actual pressure display) shows the actual parameters of the activated menu option.
4. The $Pressure_{plus}$ or $Pressure_{minus}$ key ⑥ changes the parameters of the menu options.
5. Press the Start/Stop key. The 'P' flashes again. The preselected parameter is stored.

   Another menu option can be selected using the $Flow_{plus}$ or $Flow_{minus}$ ⑦ key.
6. Turn the device off. After it has been turned on again, it is ready for use.

Menu option P0

In P0 the actual software version is showed.

Menu option P1

In P1 select the desired pressure which should automatically be activated when you use the footpedal.

On delivery, this value will reflect 150 mm Hg

Menu option P2

In P2 the actual pressure values of the pressure sensors are shown in the desired and actual pressure display. These values must correspond as much as possible (±4 mm Hg).

7 OPTIONS

7-1 Cable Remote Control

Using the cable remote control option, the physician can operate the device from the sterile field.

CAUTION !
It is only allowed to use the remote control dry and closed.

1. Activate the device with the power switch.
2. Connect the cable remote control to the socket on the front of the device.

In this case plug first the adapter, offered by the distributor, to the socket on the front of the device and then connect the cable remote control to the adapter.

3. You can activate all functions of the device with the remote control:
   - Flow — Increase and decrease the desired flow ①
   - Pressure — Increase and decrease the desired pressure ②
   - Wash — Quick change flow and pressure (function 'wash') ③
   - Start/Stop — Start/Stop the pump ④

Function 'Wash'

During operation the desired flow and desired pressure can be increased quickly using the Wash-Key. The desired flow will change automatically from the preselected (i. e. 0,75 l/min) value to the max. value of 2.0 l/min. The desired pressure value can be selected through the user menu.

1. Press the Wash-Key. The desired flow display will show '2.00' l/min and the desired pressure display will show the value selected through the user menu. The display 'Wash' will light up.
2. Press the Wash-Key again. The desired flow and desired pressure display will return to the previously selected values.

7-2 Footpedal

During operation the desired flow and desired pressure can be increased quickly using the footpedal. The desired flow will change automatically from the preselected (0.75 l/min) value to the max. value of 2.0 l/min. The desired pressure value can be selected through the user menu (P1).

1. Connect the footpedal to the connection for footpedal on the rear of the device.
2. Step on the footpedal. The desired flow display will show '2.00' l/min and the display 'Wash' will light up. The desired pressure display will show the value selected through the user menu.
3. With another step on the footpedal the desired flow and desired pressure display will return to the previously selected values.

8 FUNCTION TEST

The function test is for checking the device, the tubing set and the instruments. To guarantee safety during the operation, this test should be performed prior to each operation.

Sterilize the reusable instruments and tubing before the operation to prevent infections. Check all the single-use items before removing them from the package to ensure that the packaging is intact and that the expiration date has not been passed.

Use only an original tube set and the original accessories.

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Control of the device

1. The device is turned off.
2. Insert the tubing set (see chapter 4-3). Connect an instrument.
3. Turn the device on using the power switch. The actual pressure display shortly shows '---'. The power switch and the digital displays light up.
4. Select the following values:
   Desired pressure: 100 mm Hg
   Desired flow: 0.80 l/min
5. Press the Start/Stop button. The green Start/Stop LED lights up.
6. Fill the tubing set and the instrument or drainage cannula completely with fluid.
7. Close the instrument valve or the stopcock at the drainage cannula. The actual pressure display must indicate 100 mm Hg (±5 mm Hg) when the roller wheel comes to a standstill.

Control of the function 'wash'

1. Connect the cable remote control or footpedal (chapter 7 Options).
2. Press the Wash-Key or depress the footpedal. The desired flow display will show '2.00' l/min and the desired pressure display will show the value which was selected through the user menu (at delivery 150 mm Hg). The display 'Wash' will be illuminated.
3. Press the Wash-Key or depress the foot pedal again and the desired flow and desired pressure displays will return to the previously selected values.
4. When this value has been reached, the function control is successfully completed. The device is tested and ready to be used in the operating room.

8 FUNCTION TEST

CAUTION !
If a device defect is determined or suspected during the function test, discontinue use of the device until it has been repaired by an authorized service technician. This is also true if the device fails to maintain the indicated tolerance levels.

CAUTION !
Never use the device if it has obvious defects, especially if these involve the power plugs or the power supply connection cables. Have the device repaired by an authorized service technician.

9 USE OF THE DEVICE DURING OPERATION

This chapter provides general information about the use of the device. Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.

To guarantee the patient's safety, the device function test must be performed prior to each use.

Please read chapter 5 on safety functions carefully before using the pump, Chapter 5 explains all the safety features, visual and acoustic warnings, and the error messages in detail.

Make sure that the pump is level with the instrument. Due to hydrostatic pressure, a difference in height influences the pressure measurement (Illustr.: 9).

WARNING !
The type of irrigation fluid to be used must be decided by the physician based on the operation method to be employed!

Before the Operation

1. Select the desired pressure and flowrate.
2. Press the Start/Stop button. The roller wheel starts turning.
3. Insert the instrument or drainage cannula into the joint.

The device will adjust the process of joint distension in accordance with the preselected pressure and flow values. Once the desired pressure has been reached the actual flow will be automatically reduced.

After the Operation

1. Press the Start/Stop button. The Start/Stop LED will extinguish.
2. Turn the pump off using the power switch.
3. Remove the tubing set. Pay attention to local hygiene regulations when disposing of the tubing set.

NOTE !
When you use pumping solutions that contain sugar (high frequency use), we recommend that you use the pump to flush out the tubing set after you have removed the fluid receptacle and disconnected the instrument.

To preserve the pump and ensure its proper functioning, proper service, maintenance and storage must be provided for. To protect the patient from infections, all accessory items that come into contact with human tissue (e.g., tubing and instruments) must be sterilized.

10-1 Cleaning the Device

After each use, turn off the power switch and remove the power cable from the connection at the rear of the device.

Use a hydrous disinfecting solution to clean the exterior of the device. Follow instructions provided by the disinfectant manufacturer to determine the correct fluid concentration. Moisten a cloth with the disinfectant solution and wipe the surface of the device. Strictly avoid entry of fluid into the device.

CAUTION !
Do not sterilize the device !

10-2 Cleaning of the Reusable Silicone Tubing Set (not for USA)

Dismantle the tubing set. Wash the parts carefully with cold and warm water. After a thorough cleaning and rinsing with demineralized water, let all parts drip, and afterwards dry them with a sterilized soft cloth and swabs.

Note about the membranes

Illustr.: 10-2

Of particular importance, the membranes ② must be removed from the pressure chamber ① for cleaning. For removal of the membrane, grip the tab ⑥ and pull the membrane upwards.

CAUTION !
Remove the membranes prior to pressurized air cleaning!

Please ensure that the membrane is placed properly back into the pressure chamber (prior to sterilization).

Place the lip ③ of the membrane in the ring nut ④ of the pressure chamber. The tab ⑥ should be directly above the gap ⑤. Press the lip of the membrane into the ring nut ④. The membrane must be level with the edge of the pressure chamber. Ensure that there are exist no crimps or folds in the membrane.

10 SERVICE AND MAINTENANCE

10-3 Disinfection of the Reusable Silicone Tubing Set (not for USA)

WARNING !
Disinfection of the tubing and instruments is insufficient to achieve sterility at SAL 10^{-6}. Further sterilization is required.

Only thoroughly cleaned tubing is to be disinfected. The tubing should be put into the solution (i. e., Cidex, Johnson & Johnson Medical) separately, with all endings open. The manufacturer of the disinfectant specifies the soaking time and the appropriate solution concentration.

CAUTION !
Do not leave silicone tubing or other silicone parts in the solution for more than 30 minutes. Silicone absorbs different disinfection solutions and is damaged when subsequently sterilized in a steam autoclave.

Take the tubing set out of the solution using forceps with a soft edge. Remaining disinfection solution on the tubing should be rinsed with sterile water under sterile conditions. Dry all parts with a sterile cloth and wrap them in a separate sterile cloth. Prior to sterilization, assemble all components of the tubing set. For temporary storage, keep the tubing in a closed, sterile container.

10-4 Sterilization of Reusable Silicone Tubing Set (not for USA)

The maximum number of sterilization cycles for the tubing set is determined by the manufacturer (see tubing packaging). Never exceed the number of uses recommended by the manufacturer.

CAUTION !
Using the silicone tabs attached to the tube set record the number of sterilization cycles completed. The tube set may not be sterilized after the last silicone tab has been removed.

Sterilization in a Steam Autoclave

Only cleaned, disinfected, dried and assembled tubing should be sterilized in steam. Please follow the operation manual of the autoclave you use.

10 SERVICE AND MAINTENANCE

E

10-5 Sterilization Conditions (not for USA)

Autoclaving
Sterilization with steam must be completed under the following conditions:

Fractional vacuum procedure
134 °C / 3 bar / 5 min
272 °F / 43.5 PSI / 5 min

CAUTION !
It is the responsibility of the user to qualify any deviation from the recommended processing method. The manufacturer is not responsible for damage or injury resulting from non-adherence to the recommended processing method.

10-6 Cleaning the Autoclavable Remote Control

CAUTION !
The remote control must be opened before cleaning and sterilisation (Illustr.: 10-6).

Use a brush and only a mild, pH-neutral detergent to clean the remote control.

DANGER !
Make sure that there are no secretion residues, tissue residues or other foreign bodies on the remote control before sterilisation.

NOTE !
Make sure that the remote control is open during disinfecting and is fully rinsed by the fluid.

10-7 Sterilising the Autoclavable Remote Control

The remote control has been tested by the manufacturer for a certain number of sterilisations (exact number see label). Never exceed the number of sterilisations specified by the manufacturer.

Saturated steam sterilisation, autoclaving
Only a cleaned, disinfected, dry and open remote control can be sterilised by saturated steam. Please follow the instructions in the operating manual for your autoclave.

10-8 Sterilisation conditions for the autoclavable remote control

NOTE!
These instructions do not guarantee the sterility of the product. Your own hygiene institute remains responsible for the validation of the sterilisation and sterility.

Method	Temperature	Time
Sat. steam sterilisation	273 °F (134 °C)	5 min.
Sat. steam sterilisation	248 °F (120 °C)	20 min.

Gamma Ray and Beta-Ray sterilisation
Gamma Ray and Beta-Ray sterilisations may not be carried out.

10-9 Annual Inspection

Manufacturer's Requirement
The manufacturer stipulates that the user or a hospital technician must regularly test the device to assess its functionality and technical safety. These tests must be performed on an annual basis. The tests are described in the Annual Inspection chapter.

Regular inspections will assist in early detection of possible malfunctions, helping to preserve the device and increases its safety.

10-10 Maintenance by the Authorized Service Technician

Maintenance every two years
To guarantee the operational safety of the pump, the device must be maintenanced at regular intervals by an authorized service technician. Depending on the duration and frequency of use, the device should be maintenanced every two years. Failure to adhere to this maintenance schedule will result in the manufacturer refusing liability for the operational safety of the pump.

A sticker on the rear wall of the casing displays the latest possible date for the next maintenance check.

Authorized service technicians
All services such as alterations, repairs, calibrations, etc. may only be performed by the manufacturer or by service technicians who are authorized by the manufacturer.

Unauthorized service technicians
If an unauthorized service technician performs maintenance or any other service, the manufacturer will not accept liability for the operational safety of the device.

Liability
The manufacturer is freed from all liability for the operational safety of the device if it has been wilfully opened and unauthorized persons have performed repairs or alterations on it.

11 ANNUAL INSPECTION

Certification
The pump owner should receive a certificate from the authorized service technician for all maintenance checks or repairs. This certificate states the type and scope of the services rendered, the service date and the name of the service company. The certificate should be signed.

Technical documentation
Receipt of technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments or alterations on the device or accessories. Only an authorized service technician may perform repairs, adjustments or alterations on the device or accessories.

10-11 Replacing the Fuse

Defective fuse
If the power switch is on 'I', yet the displays and LEDs do not light up and the device does not function, then the fuse may be defective and is need of replacement.

Ensure that the mains power supply cable is properly connected to the power supply input and to a safety socket. Check if the house power supply fuse is functioning and if the voltage supply matches the specification on the fuse holder.

CAUTION !
Unplug the power supply cable from the device before checking the fuse.

1. Unfasten the snap grip of the fuse holder with a small screwdriver.
2. Pull out the fuse holder and check the fuses.
3. Insert a new fuse. Use only the prescribed fuses (see Technical Data chapter).
4. Press the fuse holder until it snaps into place.
5. Use the mains power supply cable to connect the plug at the rear of the device to the mains power socket.

Simple tests
The tests described here are designed for users or hospital technicians. The operation, function and performance of the device may be tested in a simple manner. Please document each test in the test record. Remember to sign and date the protocol (see chapter Test Record).

Values and tolerance levels
The following measuring tools and aids were used to determine the measurements and tolerance levels indicated in the chapter Technical Data:

- Tubing set
- 1 beaker tared (1.0 l)
- 1 fluid container
- Ruler 50 cm

If those values and tolerance levels are not maintained, have the device checked by authorized service personnel.

Data sheet
The manufacturer conducts a complex functions and safety test on each device prior to deliver. The results of our quality control testing are documented on the data sheet.

11-1 Safety Test

A safety test is to be completed within the framework of the annual inspection by qualified personnel.

1. Perform a visual inspection of the device. Of particular importance is:
   - The fuses are in accordance with the specifications of the manufacturer.
   - The text and labels on the device are legible.
   - The mechanical condition of the device allows for safe use.
   - No safety relevant contamination of the device exists.
2. Perform the measurement of the leakage current in accordance with DIN EN 60601-1 / IEC 601-1.
3. Perform the measurement of the protective conductor resistance in accordance with DIN EN 60601-1 / IEC 601-1. The protective conductor resistance should be measured with the power cord connected. The maximum value should reflect 0.2 Ω.
4. Perform the measurement of the insulation (resistance) with 500-700 V DC. The minimum value should reflect 50 MΩ. The measurement of rigging strength should not be performed using high voltage.

11-2 Basic Function Test

The basic function test checks the displays, keys and the performance of the device. In order to perform this test, the tubing set, a fluid container and a scaled beaker (1.0 l) are required.

11 ANNUAL INSPECTION

Preparing the Test

1. Insert the tubing set (Illustr.: 11-2).
2. The pressure chamber must snap in audibly.
3. Connect the irrigation tubing to a fluid container. The fluid container must hang 1.0 m above the device.
4. Place the instrument tubing in a beaker.
5. Turn the device on using the power switch. Select the following values:
   desired pressure: 150 mm Hg
   desired flow: 1.00 l/min
6. Press the Start/Stop button. The green Start/Stop LED lights up. The roller wheel starts turning.
7. Fill the tubing set completely with fluid and let the pump run for 1 min to finish the automatic instrument recognition.
8. Then clamp the instrument tubing closed. Do not press the Start/Stop button.

Performing the Test

1. Empty the beaker.
2. Release the clamp on the instrument tubing and time one minute.
3. At the end of this time press the Start/Stop button. The beaker must contain 1.0 l (±10%) water.

When this value has been reached, the function control is successfully completed.

11-3 Testing the Measurement of Pressure

The pressure measurement test checks the proper operation of the pressure chamber, the pressure sensors and the applied pressure. In order to perform this test, a complete tubing set and a beaker filled with water are required.

Here the height of the water column (hydrostatic pressure) is measured and the result then converted into millimetre mercury column. After the conversion, the height of the water column above the pressure chamber must correspond to the value of the actual pressure display.

Conversion formula: p (cm H_2O) x 0.74 = p (mm Hg)

1. Place the irrigation tubing into a container filled with water (Illustr.: 11-3).
2. Fill the tubing set with water up to the patient connection. Press the Stop/Start key to stop the pump.
3. Close the end of the patient tubing (close the tubing with your finger).
4. Hold the water gauge of the patient tubing's end (h) 44 cm above the pressure chamber.

The width of the device (36 cm) can serve as a measuring aid. Add the height between pressure chamber and the case upper half (8 cm) to the 36 cm. The water column reaches a total of 44 cm above the pressure chamber (44 cm H_2O x 0.74 = approx. 33 mm Hg).

5. Release the patient tubing.
6. The actual pressure display must indicate 33 mm Hg (±5 mm Hg).
7. Change the height of the water column. The indicated value of the actual pressure display must follow the change.

The test of the measurement of pressure is successfully completed when the values of the actual pressure display correspond to those of the water column.

11-4 Test of the Pressure Sensors

This test checks the correct function of the pressure sensors.

1. Remove the pressure chamber from the pump head (Illustr.: 11-4).
2. Gently touch the upper pressure sensor ① with your finger.
3. The actual pressure display indicates 'E01', the warning display 'Service' lights up, and a warning signal is heard.
4. Repeat the test with the lower sensor ② .
5. Select item P2 of the user menu. The desired pressure and actual pressure display indicate a value. These values must be the same (±4 mm Hg). If the discrepancy is larger, the device must be reset by a certified technician.

The test of the pressure sensors is completed.

Please record the successful performance of the test in the following test protocol.

12 TEST RECORD

Date	Result	Remarks	Sign

13 TECHNICAL DATA

Power Supply	100-240 V~ Mains fuse T 5 A Connection for equipotentiality
Frequency	50-60 Hz
Power Consumption	75 W
Max. Current	100 V: 1.0 A 240 V: 0.2 A
Protection Class	Class I, Type BF
Dimensions	Width x height x depth 360 x 145 x 300 [mm]
Weight	Approx. 7.5 kg
Operation Directions	10-40 °C / 50-104 °F 30-75 % rel. air humidity
Storage and Transportation Directions	-40 to +70 °C / -40 to +159 °F 10-100 % rel. air humidity
Manufactured and Tested acc. to	IEC 601-1
EMC	IEC 601-1-2
Pump Capacity	0.1-2.0 l/min
Pressure Area	0-150 mm Hg
Max. Suction Pressure	During Pressure Release 500 mm Hg
Displays	Desired pressure 0-150 mm Hg Actual pressure 0-350 mm Hg Desired flow 0.1-2.0 l/min
Accuracy of Measurement	Pressure measurement ±6 % Flow measurement ±10 %
High Pressure Safety	Engine shutdown above 250 mm Hg after 5 s
Connections	Foot pedal, pneumatic Cable remote control RS232-Serial Port

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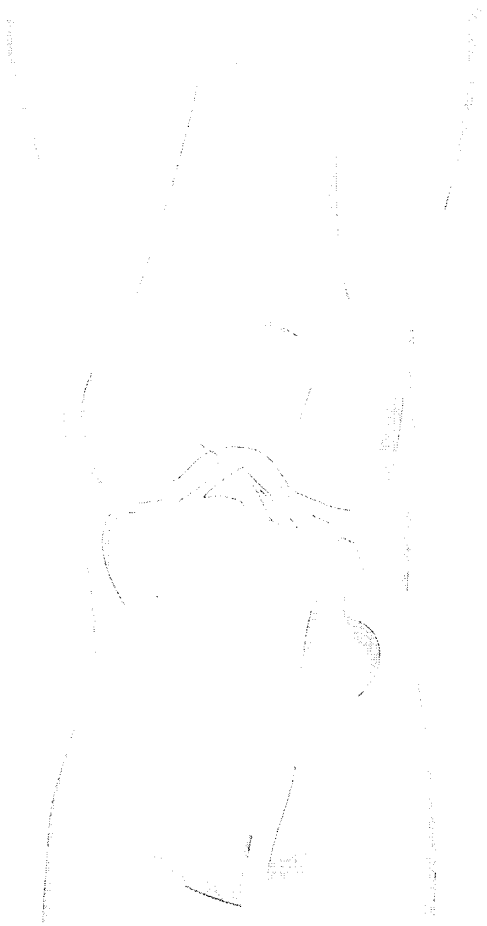
15 TROUBLESHOOTING INSTRUCTIONS

Error/Alarm Indicator	Source of Error	Elimination of Errors
Start/Stop LED flashes, three short warning signal are heard.	The pressure chamber did not snap in	Remove the pressure chamber from the pump head. Press the pressure chamber into the pump head. The pressure chamber must snap in audibly.
Service icon is lit, actual pressure display indicates 'E01', warning signal is heard	The difference between the two pressure sensors is more than 50 mm Hg	Turn the device off at the main switch and after 10 s again on. Should the error message appear again, the device is defective. Prevent all unauthorized persons from using the device. Inform the service center that they should check the device.
Service icon is lit, actual pressure display indicates 'E01', warning signal is heard	The engine control mechanism is defective	Check to see if the tube is caught in the roller wheel. Turn the device off at the power switch and after 10 s again on. Should the error message appear again, the device is defective. Prevent all unauthorized persons from using the device. Inform the service center that they should check the device.
Service icon is lit, it is possible to hear a warning signal	The device is defective.	Turn the device off at the power switch and after 10 s again on. Should the error message appear again, the device is defective. Prevent all unauthorized persons from using the device. Inform the service center that they should check the device.
The actual pressure display flashes	The intraarticular pressure exceeds the desired pressure by 30 mm Hg.	Please note that the flashing of the actual pressure display is an information for you, that the desired pressure has been exceeded.
Warning display 'overpressure' is lit the actual pressure display flashes, a warning signal is heard, the roller wheel stops	The intraarticular pressure exceeds 250 mm Hg	Reduce the intraarticular pressure. Open the drainage valve on the instrument. The device starts automatically after reducing the pressure below 250 mm Hg.
The roller wheel spins backwards	The intraarticular pressure exceeds the desired value	Please note that the automatic venting system is working to reduce intra-abdominal pressure.
Warning signal is heard	The roller wheel spins backwards	Fluid is transported out of the joints into the tubing system. Please observe the potential of contamination of the tubing set. After every use, the entire tubing set and the fluid container must be replaced.



Manuel F

Pompe d'irrigation pour l'arthroscopie